REMARKS

This Amendment and Response amends claims 1-8, 11-32, 35-53, and 56-58 and cancels, without prejudice, claims 9-10, 33-34, and 54-55. Claims 1-8, 11-32, 35-53 and 56-58 are pending after entry of this Amendment and Response. No new matter was added by these amendments. No fees are believed due; however, the Commissioner is hereby authorized to charge any deficiencies that may be required or credit any overpayment to Deposit Account Number 11-0855.

I. Claim Objections

Claim 12 is objected to because of a typographical error. Applicant has amended claim 12 to recite "22 GPa," rather than "220 GPa." Support for this amendment can be found in the specification at page 2, lines 15-16. Applicant respectfully submits that the present amendment corrects the typographical error and overcomes the objection. Accordingly, Applicant respectfully requests that the objection be withdrawn.

II. Rejection of Claims under 35 U.S.C. § 112, second paragraph

Claims 6 and 10-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended claim 6 to recite a definite limitation – at least 75% glycolic acid. Applicant respectfully submits that the present amendment overcomes the current rejection, and respectfully requests that the rejection be withdrawn.

Claims 10-12 recited the limitation "the fibers," for which there was no antecedent basis. Applicant has amended claims 10-12 to recite "the polymer composition" rather than "the fibers." Applicant respectfully submits that the present amendment overcomes the current rejection, and respectfully requests that the rejection be withdrawn.

III. Rejection of Claims under 35 U.S.C. § 102

Claims 1-12 and 17-37 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,303,697 to Yuan et al. Applicant respectfully traverses this rejection and requests that it be withdrawn.

Claim 1 of the present application recites a polymer composition that comprises a copolymer comprising at least glycolic acid and another bioresorbable monomer, the polymer composition having a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa. It is the Examiner's position that the polymers disclosed by Yuan inherently possess the mechanical properties recited in claim 1.

A rejection based on inherency is appropriate when a claim recites a function, property, or characteristic of a composition and the prior art discloses the same composition, but ***does not explicitly disclose the function, property, or characteristic***. MPEP 2112 (III). Applicant respectfully submits that the rejection of claims 1-12 and 17-37 as inherently anticipated by Yuan is improper because Yuan ***does*** explicitly disclose the mechanical properties of the polymers taught by that reference, and those mechanical properties are ***lower*** than the mechanical properties recited in claims 1 and 10-12.

Yuan discloses polymers that have tensile strengths and moduli that are ***lower*** than the tensile strength and modulus claimed in independent claim 1 of the present application. Table 2 in column 11 of Yuan lists the tensile strengths and moduli of the polymers taught by that reference. These polymers have a maximum tensile strength of 143.9 ksi (992 MPa) and a maximum modulus of 2100 ksi (14.5 GPa). The mechanical properties recited in claim 1 are not expressly or inherently disclosed in Yuan because Yuan affirmatively states that the polymers disclosed therein have lower mechanical properties than those recited in claim 1.

Additionally, Applicant respectfully submits that the application contains adequate disclosure regarding how to obtain the claimed properties and effects with only the claimed ingredients. The application describes, in detail, non-limiting examples of processes for obtaining the claimed properties. (Specification, ¶¶ [0014] – [0020].) The application also provides specific, non-limiting examples whereby fibers with the claimed properties were formed. (Specification, ¶¶ [0040] – [0041].)

Yuan specifically states that the polymers disclosed therein have properties that are not the same as the properties claimed in claim 1. As a result, Applicant respectfully submits that the properties claimed in claim 1 are not inherent in the polymers disclosed in Yuan and that Yuan does not anticipate claim 1. As claims 2-8, 11-12, 17-32, and 35-37 depend from and further limit claim 1 or an intervening dependent claim, Applicant respectfully submits that these claims are patentable for at least the same reasons that independent claim 1 is patentable and may be patentable for additional reasons. Claims 9-10 and 33-34 have been cancelled rendering their rejection moot. Accordingly, Applicant respectfully submits that claims 1-8, 11-12, 17-32 and 35-37 are in condition for allowance and respectfully requests that the present rejection be withdrawn.

IV. Rejection of Claims under 35 U.S.C. § 103(a)

Claims 13-14, 16, and 38-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yuan in view of U.S. Patent 4,700,704 to Jamiolkowski et al. (hereinafter "Jamiolkowski"). Claim 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Yuan in view of Jamiolkowski and further in view of Okuzaki et al., Journal of Polymer Science: Part B: Polymer Physics 1999, 37, 991-996 (hereinafter "Okuzaki"). Claims 54 and 55 have been cancelled, rendering their rejection moot. Applicant respectfully traverses the rejections of claims 13-16, 38-53, and 56-58 and requests withdrawal thereof.

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex*, Federal Register, Vol. 72, No. 195, p. 57527 (October 10, 2007) explain what is required where an obviousness rejection is made:

> As reiterated by the Supreme Court in *KSR,* the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deer Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:
>
> (1) Determining the scope and content of the prior art;
>
> (2) Ascertaining the differences between the claimed invention and the prior art; and
>
> (3) Resolving the level of ordinary skill in the pertinent art.

> Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. . . .
>
> Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquires. . . . Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. . . .
>
> Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C 103.

Applicant respectfully submits that the July 28, 2008 Office Action fails to comply with these requirements. Specifically, the Examiner has failed to make and articulate findings of fact that support an obviousness rejection under 35 U.S.C. § 103. As discussed previously, claim 1 recites a polymer composition that comprises a copolymer composition comprising at least glycolic acid and another bioresorbable monomer and that has a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa. The rejected claims all depend from claim 1; therefore, the rejected claims all incorporate the limitations recited in claim 1 and require a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa. It is the Examiner's position that, regarding claim 13 (from which rejected claims 14-16 and 38-58 depend), Yuan teaches the claimed composition (i.e. set forth in claim 1) and the steps of forming a fiber comprising a PLA/PGA copolymer and subjecting the fiber to a drawing procedure. The Examiner acknowledges that Yuan does not teach quenching the fibers, but argues that Jamiolkowski cures the deficiency by teaching a different polymer composition, also comprising PGA, that is melt spun, extruded, quenched, and drawn. For the reasons explained in detail below (A) the combination of the cited prior art references is improper because one of skill in the art would have no reasonable expectation of success in combining the cited references to achieve the compositions of the present invention; (B) the combination of the cited prior art references is improper because the references teach away from their combination; and (C) the cited references, singly or in combination, do not teach or suggest each and every element of the claims.

A. One of skill in the art would have no reasonable expectation of success in combining the cited references to achieve the compositions of the present invention.

A finding of obviousness requires a reasonable expectation of success. MPEP 2143.02 (I). A person of skill in the art would have no reasonable expectation of success in combining Yuan and Jamiolkowski or Yuan, Jamiolkowski, and Okuzaki to arrive at claims 13-16, 38-53 and 56-58.

The prior art references cited by the Examiner teach polymers having maximum tensile strengths of 992 MPa (Yuan), 786 MPa (Jamiolkowski), and 275 MPa (Okuzaki). These polymers have maximum moduli of 14.5 GPa (Yuan), 7.8 GPa (Jamiolkowski), and 9.1 GPa (Okuzake). None of the cited references teaches a polymer having a tensile strength of at least 1100 MPa or a modulus of 20 GPa as recited in claim 1. Accordingly, one of skill in the art would not reasonably expect success in achieving the claimed polymer compositions by combining the prior art cited by the Examiner.

Yuan describes processes that provide polymers with a maximum tensile strength of 992 MPa and a maximum modulus of 14.5 GPa. Yuan teaches processes that include forming fibers, for example by solution spinning or extrusion, and orienting the fibers, for example by drawing. Yuan does not teach or suggest a quenching step and does not teach or suggest any step that might provide fibers with a higher strength than those reported in that reference.

Jamiolkowski describes polymers that have moderate strength (206.8 MPa to 786 MPa) and a low modulus (7.8 and preferably less than 2.4 GPa). These polymers are used for synthetic absorbable sutures. Jamiolkowski teaches processing the polymers by melt spinning the polymers and taking up the extrudate through ice water, i.e. quenching. Jamiolkowski does not teach or suggest the effect of the quenching step on the tensile strength of the polymer. Importantly, Jamiolkowski does not teach or suggest that the quenching step contributes to a higher tensile strength or modulus. On the contrary, the polymers taught by Jamiolkowski have a lower tensile strength than the polymers taught by Yuan.

Because the polymers taught by Jamiolkowski have a ***lower*** tensile strength and modulus than the polymers of Yuan, one of skill in the art who started with Yuan would not expect to ***increase*** the mechanical properties of the Yuan polymers by using the teachings of Jamiolkowski. In particular, one of skill in the art would not reasonably expect that the mechanical properties of the polymers of Yuan could be increased by adding the quenching step of Jamiolkowski. One of skill in the art would more likely expect that adding the quenching step of Jamiolkowski would result in lower mechanical properties because the polymers disclosed by Jamiolkowski have lower mechanical properties than those disclosed by Yuan. Accordingly, one of skill in the art would have no reasonable expectation of success in combining the teachings of Yuan and Jamiolkowski to provide the polymers of claim 1, which have a higher strength, at least 1100 MPa, than the polymers taught by Yuan, Jamiolkowski, and Okuzaki.

Applicant respectfully submits that the combination of Yuan and Jamiolkowski is based on hindsight reconstruction of Applicant's own invention and that one of skill in the art would have no reasonable expectation of success in combining the cited references to achieve the compositions of claims 13-16, 38-53, and 56-58. As a result, Applicant respectfully submits that claim 1 is patentable over Yuan in view of Jamiolkowski and over Yuan in view of Jamiolkowski, further in view of Okuzaki. As claims 13-16, 38-53, and 56-58 depend from and further limit claim 1 or an intervening dependent claim, Applicant respectfully submits that these claims are patentable for at least the same reasons that independent claim 1 is patentable and may be patentable for additional reasons.

Accordingly, Applicant respectfully submits that claims 13-16, 38-53, and 56-58 are in condition for allowance and respectfully request that the present rejection be withdrawn.

B. The references teach away from their combination.

Applicant respectfully submits that Yuan and Jamiolkowski are not properly combinable references. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983).

The invention disclosed in Yuan is designed for use in fracture fixation. Yuan states that the polymers disclosed therein have superior mechanical properties and that higher

values of tensile modulus and tensile strength are retained during the processing techniques disclosed by that reference. The values of modulus and strength disclosed by Yuan are up to 992 MPa and 14.5 GPa respectively. In one example provided by Yuan, a drop in modulus to 11.0 GPa is described as a very high drop. So, high modulus and tensile strength are important to the invention of Yuan.

On the other hand, Jamiolkowski provides copolymers that have a maximum tensile strength of only 786 MPa. Importantly, while Jamiolkowski discloses polymers that have a modulus up to 7.8 GPa, Jamiolkowski teaches that preferred polymers have a modulus of ***less than 2.4 GPa***. This combination of moderate tensile strength and low modulus is important so that the copolymers have the desired strength, compliance, and flexibility required for suture materials.

Because Jamiolkowski teaches that the modulus of the polymers disclosed therein are preferably lower than 2.4 GPa, and Yuan teaches that a much higher modulus is desired, both references teach away from their combination. Thus, the combination of Yuan and Jamiolkowski is improper and cannot render claims 13-16, 38-53, and 56-58 obvious.

Accordingly, Applicant respectfully submits that claims 13-16, 38-53, and 56-58 are in condition for allowance and respectfully request that the present rejection be withdrawn.

C. The cited references, singly or in combination, do not teach or suggest each and every element of the claims.

Neither the combination of Yuan and Jamiolkowski nor the combination of Yuan, Jamiolkowski, and Okuzaki produces the claimed invention at least because none of the cited prior art references teaches or suggests a polymer having a tensile strength of at least 1100 MPa. As stated previously, claim 1 of the present application recites a polymer composition having a tensile strength of at least 1100 MPa. Claims 13-16 and 38-58 depend from and further limit claim 1. As discussed in section III above, the polymers disclosed by Yuan have a maximum tensile strength of 992 MPa and a maximum tensile modulus of 14.5 GPa. Accordingly, Yuan does not disclose or suggest a polymer having a tensile strength of at least 1100 MPa and tensile modulus of at least 20 GPa. The polymers disclosed in Jamiolkowski have a maximum tensile strength of 786 MPa and a maximum tensile modulus

of 7.8 GPa, so Jamiolkowski also does not disclose or suggest a polymer having a tensile strength of at least 1100 MPa and tensile modulus of at least 20 GPa. The polymers disclosed by Okuzaki have a maximum tensile strength of 275 MPa and a maximum tensile modulus of 9.1 GPa. So, Okuzaki also does not disclose or suggest a polymer having a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa. Thus, none of the cited prior art references teaches a polymer having a tensile strength of at least 1100 MPa and a tensile modulus of at least 20 GPa.

As a result, Applicant respectfully submits that claim 1 is patentable over Yuan in view of Jamiolkowski and over Yuan in view of Jamiolkowski, further in view of Okuzaki. As claims 13-16, 38-53, and 56-58 depend from and further limit claim 1 or an intervening dependent claim, Applicant respectfully submits that these claims are patentable for at least the same reasons that independent claim 1 is patentable and may be patentable for additional reasons.

Furthermore, claim 13, from which claims 14-16, 38-53, and 56-58 depend, recites drawing a localized region of the fibers. None of the cited prior art references discloses or suggests a drawing step in which a localized region of the fibers is drawn.

Applicant respectfully submits that claim 13 is patentable over Yuan in view of Jamiolkowski and over Yuan in view of Jamiolkowski, further in view of Okuzaki. As claims 14-16, 38-53, and 56-58 depend from and further limit claim 13 or an intervening dependent claim, Applicant respectfully submits that these claims are patentable for at least the same reasons that claim 13 is patentable and may be patentable for additional reasons

Accordingly, Applicant respectfully submits that claims 13-16, 38-53, and 56-58 are in condition for allowance and respectfully request that the present rejection be withdrawn.

V. Rejection of Claims based on Double Patenting

Claims 1-53 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 2-33 of copending U.S. Patent Application No. 10/472,908.

Applicants respectfully request that this issue be deferred until the claims in the present application are in condition for allowance. At such time Applicants will file an appropriate terminal disclaimer if necessary.

CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed July 28, 2008. Applicant asserts that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by the Examiner's amendment, or that there are any other issues that can be resolved by a telephone interview, a telephone call to the undersigned at 404-815-6040 is respectfully solicited.

Respectfully submitted,

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